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| JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017 | | | EXAMINER VATHYAM, SUREKHA | |
| | | | ART UNIT 1753 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/629,524

Applicant(s)

LAU, ALDRICH N.K.

Examiner

Surekha Vathyam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-26 and 28-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-26 and 28-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/02/04, 5/18/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 24 – 26 and 28 – 51 in the reply filed on 23 April 2007 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 24 – 26, 28 – 29 and 31 – 51 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 2002/00746 which corresponds to Viovy et al. (US 2004/0101970). All paragraph numbers herein refer to the US publication.

Regarding claims 24 and 40, WO ('746) discloses a method for separating a mixture of biomolecules ([0025]), comprising: (1) contacting a composition comprising a buffer ([0029], [0157] – [0158]) and an effective amount of a poly (M_1 -g- M_2) or a salt thereof ([0040], [0071], [0162] – [0163]) wherein: each M_1 is N,N-dimethyl-acrylamide, each M_2 is acrylamide, provided that at least one M_1 is different from at least one M_2 ([0071]), with a mixture comprising a biomolecule ([0025], [0157] – [0163]); and (2)

applying an electric field to the composition in an amount sufficient to facilitate the separation of a biomolecule from the mixture ([0006]).

Regarding claims 25 and 41, WO ('746) discloses the method wherein the separation is performed within a capillary tube ([0006], [0031], [0101] – [0103], [0121] – [0123]). The examiner acknowledges that the universe has two or more biomolecules that are polynucleotides.

Regarding claims 26 and 42, WO ('746) discloses the method wherein the separation has a crossover of at least 400 base pairs (see fig. 7 and [0124], [0165] – [0170]).

Regarding claims 28 and 43, WO ('746) discloses the method wherein the composition further comprises a sieve polymer ([0099], [0124] – [0130]).

Regarding claims 29 and 44, WO ('746) discloses the method wherein the sieve polymer is poly(acrylamide) ([0099], [0124] – [0130]).

Regarding claims 31 and 45, WO ('746) discloses the method wherein the poly(M₁-g-M₂) or a salt thereof has a weight-average molecular weight of from about 150,000 Daltons to about 20 Mdaltons ([0047]).

Regarding claims 32 and 46, WO ('746) discloses the method wherein the composition further comprises a sieve polymer or a salt thereof having a weight-average molecular weight of from about 100,000 Daltons to about 5 MDaltons ([0124]).

Regarding claims 33 and 47, WO ('746) discloses the method wherein the sieve polymer is substantially linear poly(acrylamide) ([0124] – [0125])/

Regarding claims 34 and 48, WO ('746) discloses the method wherein the buffer is an aqueous buffer ([0029], [0084], [0124] – [0130], [0157] – [0163]).

Regarding claims 35 and 49, WO ('746) discloses the method wherein the composition has a pH of from about 5 to about 11 ([0029], [0124] – [0125]).

Regarding claims 36 and 50, WO ('746) discloses the method wherein the composition has a pH of from about 7 to about 10 ([0029], [0124] – [0125]).

Regarding claims 37 and 51, WO ('746) discloses the method wherein the composition further comprises formamide, urea, pyrrolidone, N-methylpyrrolidone or a mixture thereof ([0029], [0124] – [0125]).

Regarding claim 38, WO ('746) discloses the method wherein the composition further comprises urea ([0029], [0124] – [0125]).

Regarding claim 39, WO ('746) discloses the method wherein the composition further comprises formamide ([0029]).

4. Claims 24 – 26 and 28 – 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Tan et al. (US 6,787,016).

Regarding claims 24 and 40, Tan ('016) discloses a method for separating a mixture of biomolecules (column 1, lines 15 – 26) comprising: (1) contacting a composition comprising a buffer (column 6, lines 59 - 61) and an effective amount of a poly (M_1 -g- M_2) or a salt thereof (column 5, lines 17 – 29, column 5, line 48 – 66) wherein: each M_1 is N,N-dimethyl-acrylamide, each M_2 is acrylamide, provided that at least one M_1 is different from at least one M_2 (column 5, line 48 – 66), with a mixture

comprising a biomolecule (column 1, lines 15 – 28 and column 11, line 48 – column 12, line 4); and (2) applying an electric field to the composition in an amount sufficient to facilitate the separation of a biomolecule from the mixture (column 1, lines 28 – 31, column 9, lines 40 – 60).

Regarding claims 25 and 41, Tan ('016) discloses the method wherein the separation is performed within a capillary tube (column 1, lines 38 – 41).

Regarding claims 26 and 42, Tan ('016) discloses the method wherein the separation has a crossover of at least 400 base pairs (see figs. 2A – 5 and column 13, lines 24 – 59).

Regarding claims 28 and 43, Tan ('016) discloses the method wherein the composition further comprises a sieve polymer (column 5, lines 30 – 47).

Regarding claims 29 and 44, Tan ('016) discloses the method wherein the sieve polymer is poly(acrylamide) (column 5, lines 30 – 47, column 11, lines 5 – 47).

Regarding claim 30, Tan ('016) discloses the method wherein the sieve polymer is poly(N,N-dimethyl-acrylamide) (column 14, line 67 – column 15, line 3) and the sieve polymer has a weight-average molecular weight of at least about 3 MDaltons (column 5, lines 31 – 35).

Regarding claims 31 and 45, Tan ('016) discloses the method wherein the poly(M₁-g-M₂) or a salt thereof has a weight-average molecular weight of from about 150,000 Daltons to about 20 Mdaltons (column 5, lines 31 – 35).

Regarding claims 32 and 46, Tan ('016) discloses the method wherein the composition further comprises a sieve polymer or a salt thereof having a weight-

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average molecular weight of from about 100,000 Daltons to about 5 MDaltons (column 5, lines 30 – 47).

Regarding claims 33 and 47, Tan ('016) discloses the method wherein the sieve polymer is substantially linear poly(acrylamide) (column 5, lines 30 – 47, column 10, line 52 – column 11, line 47).

Regarding claims 34 and 48, Tan ('016) discloses the method wherein the buffer is an aqueous buffer (column 6, line 59 – column 7, line 2, column 10, lines 23 – 27).

Regarding claims 35 and 49, Tan ('016) discloses the method wherein the composition has a pH of from about 5 to about 11 (column 6, line 59 – column 7, line 2, column 10, lines 23 – 27).

Regarding claims 36 and 50, Tan ('016) discloses the method wherein the composition has a pH of from about 7 to about 10 (column 6, line 59 – column 7, line 2, column 10, lines 23 – 27).

Regarding claims 37 and 51, Tan ('016) discloses the method wherein the composition further comprises formamide, urea, pyrrolidone, N-methylpyrrolidone or a mixture thereof (column 7, lines 2 – 10, column 11, lines 5 – 47).

Regarding claim 38, Tan ('016) discloses the method wherein the composition further comprises urea (column 7, lines 2 – 10, column 11, lines 5 – 47).

Regarding claim 39, Tan ('016) discloses the method wherein the composition further comprises formamide (column 7, lines 2 – 10).

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2002/00746 which corresponds to Viovy et al. (US 2004/0101970) in view of Tan et al. (US 6,787,016). All paragraph numbers herein refer to the Viovy et al. US publication.

WO ('746) discloses the method as discussed with regards to claim 28 above. Regarding claim 30, WO ('746) discloses the method wherein the sieve polymer is poly(N,N-dimethyl-acrylamide) ([0125] – [0130]) but does not expressly disclose its weight-average molecular weight.

Tan ('016) teaches a method for separating a mixture of biomolecules (column 1, lines 15 – 26) comprising: (1) contacting a composition comprising a buffer (column 6, lines 59 - 61) and an effective amount of a poly (M_1 -g- M_2) or a salt thereof (column 5, lines 17 – 29, column 5, line 48 – 66) wherein: each M_1 is N,N-dimethyl-acrylamide, each M_2 is acrylamide, provided that at least one M_1 is different from at least one M_2

(column 5, line 48 – 66), with a mixture comprising a biomolecule (column 1, lines 15 – 28 and column 11, line 48 – column 12, line 4); and (2) applying an electric field to the composition in an amount sufficient to facilitate the separation of a biomolecule from the mixture (column 1, lines 28 – 31, column 9, lines 40 – 60). Tan ('016) further teaches the method wherein the composition further comprises a sieve polymer wherein the sieve polymer is poly(acrylamide) (column 5, lines 30 – 47, column 11, lines 5 – 47). Tan ('016) also teaches the method wherein the sieve polymer is poly(N,N-dimethyl-acrylamide) (column 14, line 67 – column 15, line 3) and the sieve polymer has a weight-average molecular weight of at least about 3 MDaltons (column 5, lines 31 – 35).

It would have been obvious to one of ordinary skill in the art to modify the method of WO ('746) to use the poly(N,N-dimethyl-acrylamide) having a weight-average molecular weight of at least about 3 MDaltons as taught by Tan ('016) because it is water soluble and functions well as a sieving polymer due to its hydrophilicity (column 5, lines 35 – 38).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chu et al. (US 6,770,698) discloses graft copolymer composition used in the separation of biomolecules by applying an electric field comprising acrylamide and N,N-dimethyl-acrylamide in buffer and additionally discloses a sieving polymer.

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Benoit et al. (US 2003/0085127) discloses a sieving polymer comprising poly (N,N-dimethylacrylamide) of high molecular weight.


Voss et al. (US 6,706,162) discloses separation method for biomolecules comprising acrylamide polymers in combination with ultra high molecular weight sieving polymers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Surekha Vathyam whose telephone number is 571-272-2682. The examiner can normally be reached on 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SV/
May 30, 2007


NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700